GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

UNSTARRED QUESTION NO:2607
ANSWERED ON:18.08.2006
CLINICAL RESEARCH .
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Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) Whether India is rapidly becoming clinical research hub in the World and the outsourcing market in India has gone up;

(b) If so, the details thereof; and

(c) The steps taken by the Government to encash this advantage?

Answer

MINISTER OF SCIENCE AND TECHNOLOGY AND MINISTER OF EARTH SCIENCES (KAPIL SIBAL)

(a)&(b) Yes, Sir. India is rapidly becoming clinical research hub in the World which is evident by the opening up of the Indian market to multinational pharmaceutical companies for conducting clinical trials on new drugs which have passed through Phase I studies in the country of origin. Such trials can be accomplished with the expertise available in India at a much lower cost than in developed countries. Outsourcing of clinical trials to India is part of a larger globalization and knowledge economy process which, along with its potential benefits, seems set to proceed as the dominant theme of global development over the near future.

(c) As there is potential for mutual benefit, it would be desirable to capture the clinical trials` outsourcing opportunity in a manner that enables economic returns to India and the multinational companies, as well as tangible benefits to public health without any exploitation. Certain country specific issues such as lack of clear regulatory norms and Intellectual Property Right (IPR) issues were earlier considered barriers to global clinical research development in India. Now, Government has streamlined the provisions under Drugs and Cosmetics (D&C) Rules concerning conduct of clinical trials in the country. Rules 122A to E of the D&C Rules have been amended for this purpose laying down mandatory requirements for prior permission to conduct clinical trials and powers to withdraw a trial. The term `clinical trial` has been defined under the rules. Schedule-Y under the rules that prescribes the requirements for pre-clinical and clinical studies concerning new drugs has been extensively revised in January, 2005, to define the responsibilities of sponsors, clinical investigators and ethic committees. The requirements of Good Clinical Practice (GCP) guidelines published by the Government have been made mandatory.